OCT 0 9 2002

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

General Provisions	Trade Name: RITA® System Common/Classification Name: Electrosurgical Radiofrequency Generator and Electrosurgical Devices
Name of Marketed Device	RITA Medical Systems Inc. – RITA® System (K983214, K992693, K993944, K003676) Radionics – Radiofrequency system (K963577, K965182, K980430, K982489)
Classification	Class II
Performance Standards	The FDA under section 514 of the Food, Drug and Cosmetic Act has not established performance standards.
Intended Use	The RITA® System (RF generator and electrosurgical devices) supplies energy for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including: • the partial or complete ablation of non-resectable liver lesions and • the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.
Device Description	The RITA System (RF Generator and electrosurgical devices) is designed to create coagulative necrotic lesions in soft tissue, and allow localized delivery of fluid to the lesion. The RF Generator is specifically designed for use with RITA Electrosurgical Devices (Accessories). The RF Generator provides multiple temperature sensors, impedance, and power monitoring to assist the user in delivering the desired energy to the target tissue. The electrosurgical devices consist of monopolar electrosurgical devices that include disposable electrosurgical probes with deployable needle arrays that deliver RF power with temperature and impedance monitoring to ablate predictable volumes of tissue.
Performance Data	Bench studies were conducted to determine the effect the bone environment has on ablation characteristics and to determine ablation parameters. Clinical studies were conducted to determine the safety and effectiveness of the RITA System for the ablation of painful bone lesions in order to alleviate pain. All of the studies were conducted on patients with lesions that had metastasized to one or more locations in the skeleton. The RITA System was used in patients who had failed conventional therapies (e.g., analgesics, radiation therapy). Effectiveness was measured using an instrument validated for evaluating cancer pain. From baseline to week four, 75% and 80% patients experienced at least a two-point reduction is worst pain and average pain respectively. The ablation procedure had low attendant morbidity (no reports of death related to use of the devices) and three adverse events potentially related to RF ablation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

Ms. Erin Mazzone
RITA Medical Systems, Inc.
Director, Regulatory Affairs
967 N. Shoreline Boulevard
Mountain View, California 94043

Re: K021329
Trade/Device Name: RITA® System
Regulatory Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device And Accessories
Regulatory Class: II
Product Code: GEI
Dated: July 30, 2002
Received: July 31, 2002

Dear Ms. Mazzone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known) K021329

Device Name RITA® System

The RITA® System (RF generator and electrosurgical devices) supplies energy for use in electrosurgery and is indicated for use in percutaneous, laparoscopic, or intraoperative coagulation and ablation of soft tissue, including:

- the partial or complete ablation of non-resectable liver lesions and
- the palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard pain therapy.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____

(per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021329